

# **Service Area Plan**

*Department of Health*

*Local Laboratory and Pharmacy Services (44017)*

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## **Service Area Background Information**

# Service Area Plan

## Department of Health

### Local Laboratory and Pharmacy Services (44017)

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#### Service Area Description

Laboratory and pharmacy services are essential to enable local health departments to diagnose and effectively treat communicable diseases, monitor other reportable conditions, as well as to diagnose and treat chronic diseases, and to respond to public health emergencies. The capacity and complexity of both of these support services varies based on the volume and complexity of laboratory tests and prescriptions and also resources available to local health departments. All local health departments maintain core competencies in inventory and proper storage of drugs and biologicals; ordering, and dispensing pharmaceuticals; provision of immunizations; specimen collection of human fluids or tissue: milk and food sampling; animal head collection for rabies testing; water sample collection; and processing and transporting of specimens for testing by private sector laboratories. These competencies are available in every locality to support prevention, diagnosis, and treatment of reportable diseases; assurance of prenatal and post partum care; wellness in infants and children; performance of environmental health assessments, assuring safe food and drinking water, and disposal of human waste.

All laboratory activities are performed in accordance with the Local Health Department's Clinical Laboratory Improvement Amendments (CLIA) certificate and all pharmacy activities comply with the Virginia Board of Pharmacy regulations and VDH policies and procedures. The local health director is responsible for assuring their lab and pharmacy services comply.

#### Local Laboratory Services

The vast majority of local health departments (97 of 119 LHDs) do only simple tests such as urinalysis and blood hemoglobin in support of services such as well-child examinations and basic communicable disease testing. These types of routine tests are best provided on-site in the interest of timely care for the clients. Additional lab testing not performed by these LHDs are purchased from private sector labs under state contract.

Those local health departments with moderate and high complexity labs (22 of 119) perform more extensive testing in support of clinical programs such as Sexually Transmitted Disease (STD) diagnosis and prenatal care. Such labs tend to be located in local health departments who have historically had large clinical programs such as primary care for adults.

More specialized testing, such as identification of uncommon pathogens in outbreaks, testing of animals for rabies, the newborn screening program and testing of specimens for tuberculosis are conducted at the Division of Consolidated Laboratories in Richmond. As a highly specialized laboratory, DCLS does not conduct the simple, routine tests that can be done by LHDs or contract laboratories. The testing done in LHDs and by DCLS complement one another and are not duplicative. In addition, the LHDs are reimbursed by Medicaid based on VDH's status as a provider of clinical services. DCLS is not eligible to bill Medicaid.

All public and private sector laboratories are regulated through the Clinical Laboratory Improvement Amendments (CLIA) of 1988 administered by the federal Centers for Medicare and Medicaid Services (CMS). Laboratories subject to CLIA regulation are those designated as moderate or high complexity based on the types of tests that are performed. The inspection of these labs is carried out by the Office of Quality Health Care and Consumer Services under contract to CMS. As of 2003 (most recent data) the 97 LHDs that perform few lab tests of low complexity are not subject to CLIA and are considered 'waived' labs.

#### Local Pharmacy Services

All 119 local health departments can provide some minimal level of prescription drug dispensing, such as

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contraceptives and STD treatment, under protocols established by local health directors and the VDH Central Pharmacy located in Richmond. Each local health department is also capable of dispensing and administering vaccines and medications in the event of an emergency as declared by the Governor.

Seven local health departments operate full service pharmacies that comply with all Board of Pharmacy Regulations. These LHDs employ pharmacists who fill prescriptions for clients who seek health care services in the health department clinics. These pharmacies do not provide services to the community at large, but only to patients who receive services from local health departments.

As a government agency, VDH purchases prescription drugs through federal contracts and multi-state purchasing compacts at prices that are substantially lower than average wholesale prices. As a condition of this preferential pricing, public health facilities are prohibited from competing against public retail entities for non-public health treatments under the federal Robinson-Patman Act. Subject to available staff, LHDs assist indigent patients to gain access to free medications available through patient assistance programs operated by pharmaceutical companies.

LHDs that have full-service pharmacies are those that have historically have operated large primary care clinics for indigent adults or who provide specialized services to such populations as children with special health care needs and newcomers to this country who are at risk for communicable diseases such as tuberculosis. As with laboratory services, such LHDs must have the resources available to support such an operation. Inspections of these pharmacies are conducted by the Board of Pharmacy.

For the majority of LHDs that do not operate pharmacies in the LHD, the prescription needs of their patients are met through the VDH Central Pharmacy. These services include: treatment or support for sexually transmitted and communicable diseases, prenatal services, family planning, provision of vaccines to all local health departments under the Virginia Vaccines for Children Program, provision of pharmaceuticals to HIV infected patients under the AIDS Drug Assistance Program; provision of pharmaceuticals in support of the Children Specialty Services Program; provision of pharmaceuticals in support of the Hemophilia Program; provision of vaccines to local health departments that do not have a pharmacy to support immunization for foreign travel; provision of pharmaceuticals in response to natural emergencies, national emergencies, and bioterrorism related events; and provision of guidance and information to local health departments on State and Federal laws that pertain to the storage, distribution, and dispensing of medications.

#### **Service Area Alignment to Mission**

This service area aligns with the VDH mission to promote and protect the health of Virginians by assuring local capacity for laboratory and pharmacy support services to detect, prevent, and treat diseases, promote health, and investigate public health emergencies.

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#### **Service Area Statutory Authority**

Chapter 2 of Title 32.1 of the Code of Virginia pertains to the reporting and control of diseases.

- Articles 1 through 3.1 of that Chapter define the authority for this particular Service Area and include reporting of disease, investigation of disease, disease control measures, quarantine, isolation of persons with communicable diseases, and control of rabies.
- § 32.1-36 of the Code of Virginia and 12 VAC 5-90-80 and 12 VAC 5-90-90 of the Board of Health Regulations for Disease Reporting and Control mandate reporting of specific diseases.
- § 32.1-37.2 requires that partner notification services (partner counseling and referral services) be offered to individuals who test positive for HIV.
- § 32.1-39 provides for STD surveillance, investigation of reports, and conducting counseling and contact tracing (partner notification).
- § 32.1-46 provides for the immunization of children against certain diseases in accordance with regulations established by the Board of Health and the implementation of a statewide immunization registry.
- Title 23, Chapter 1, § 23-7.5 requires full time students enrolling in public institutions to be immunized against certain diseases in accordance with the recommendations of the American College Health Association.
- § 32.1-57 through 32.1-60 requires STD examination, testing, and treatment.

#### **Service Area Customer Base**

Customer(s)	Served	Potential
Children receiving services through local health departments	50,844	90,000
Children with special health care needs receiving care coordination services	5,538	190,600
Children with special health care needs served through VDH child development clinics	3,144	49,300
Citizens with reportable animal bites	73,206	7,400,000
Citizens with Reportable Diseases	37,094	7,400,000
Uninsured citizens	148,292	1,095,000
Women of childbearing age at or below the 200% income poverty level	73,206	173,700

#### **Anticipated Changes In Service Area Customer Base**

- Assessments of community health needs may result in identification of new constituencies for services as health service gaps are identified
- Updates in state and federal regulatory guidelines could expand our mandate for services, restrict access to services or change the ability to utilize specific vendors and contracts for laboratory and pharmacy services.
- Social, economic, political, and technological changes will create variations in customer base, priorities, and advances in laboratory and pharmaceutical products with resultant cost increases.
- Global migration continues to diversify the customer base in terms of special health care needs and the need to communicate with non-English speaking customers.
- Partnering opportunities with other agencies that are likewise impacted by the above factors who may turn to public health to provide quality and cost effective laboratory and pharmacy services to eligible customers.

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#### **Service Area Products and Services**

- Diagnosis of Organism or Medical Condition:
  - Collection of human and environmental specimens
  - Processing, transporting, and evaluating specimens
  - Reporting laboratory results to Clinicians, Nurses, and Environmental Health Specialists
  - Collectively analyzing reportable disease for surveillance and tracking
- Consultation and Education:
  - Counseling patients on the meaning of laboratory results
  - Educating private providers on interpretation of laboratory results
  - Educating the public on the significance of laboratory reports
  - Educating providers on how to manage outcomes based on laboratory findings
  - Training of Nurses, Physician Assistants, and other health care providers
- Treatment:
  - Dispensing medications by licensed clinicians or pharmacists
  - Administering pharmaceuticals to prevent disease
  - Educating patients about side effects and adverse reactions
  - Linking citizens to affordable pharmaceuticals for chronic disease management in the private sector
- Rapid Emergency Response:
  - Maintenance of documentation of reports and chain of custody of specimens
  - Provide prophylaxis to exposed contacts of communicable disease outbreaks
  - Collaborate with partners to ensure capacity for rapid response to identify/diagnose suspected biological or chemical agent and to provide mass immunizations or treatments

#### **Factors Impacting Service Area Products and Services**

- A downturn in the economy may increase the demand for services if there is an increase in the number of underinsured or uninsured citizens, who turn to the local health department for services.
- Maintenance of trained staff is challenging as competition from private sector for trained pharmacy staff increases and proficiency requirements for laboratory staff increase.
- Immunization of foreign born non-English speaking persons and world travel creates more diagnostic and treatment burden to local health departments.

#### **Anticipated Changes To Service Area Products and Services**

- Availability of pharmaceutical supplies (example: flu vaccine) will vary and affect product and service availability.
- Availability of enhanced laboratory testing can dramatically increase the accuracy and timeliness of disease detection.
- Existence of anthrax screening devices in large postal facilities will necessitate the ability to quickly respond to predicted number of false positives.
- Increasing demand for affordable medications requires local Health Department staff to provide more linkages to needed resources.

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#### **Service Area Financial Summary**

The majority (54 percent) of funding for Laboratory and Pharmacy services comes from state general funds. Federal funds, the collection of fees assessed on customers and miscellaneous sources such as grants, contracts and donations comprise the remaining 46 percent.

	<b><u>Fiscal Year 2007</u></b>		<b><u>Fiscal Year 2008</u></b>	
	<b>General Fund</b>	<b>Nongeneral Fund</b>	<b>General Fund</b>	<b>Nongeneral Fund</b>
<b>Base Budget</b>	\$5,025,799	\$4,346,452	\$5,025,799	\$4,346,452
<b>Changes To Base</b>	\$545,368	\$354,929	\$545,368	\$354,929
<b>SERVICE AREA TOTAL</b>	<b>\$5,571,167</b>	<b>\$4,701,381</b>	<b>\$5,571,167</b>	<b>\$4,701,381</b>

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## Service Area Objectives, Measures, and Strategies

### Objective 44017.01

#### ***Assure access to quality pharmaceutical services in support of public health***

Local health departments assure citizens local access to needed immunizations and pharmaceuticals to promote the health of pregnant women and children, and treat and prevent diseases. The Virginia Board of Pharmacy regulates all local health department pharmacies and conducts periodic inspections to assure adherence to statutory regulations contained in the Code of Virginia. Local health directors and Pharmacist in Charge will assure that their respective pharmacies adhere to all regulatory requirements, and comply with quality standards.

#### **This Objective Supports the Following Agency Goals:**

- Prevent and control the transmission of communicable diseases.  
( )
- Collaborate with partners in the health care and human services system to assure access to quality health care and human services.  
( )
- Respond in a timely manner to any emergency impacting public health through preparation, collaboration, education and rapid intervention.  
( This objective also aligns with Virginia's long term objectives to protect the public's safety and security, ensuring a fair and effective system of justice and providing a prepared response to emergencies and disasters of all kinds)

#### **This Objective Has The Following Measure(s):**

- **Measure 44017.01.00**

##### ***Dispensing error rate***

**Measure Type:** Outcome      **Measure Frequency:** Annually

**Measure Baseline:** New measure, baseline to be determined by July 1, 2006.

**Measure Target:** Less than 0.75 errors per 1,000 filled prescriptions by end of FY08.

**Measure Source and Calculation:**

2005 VDH Risk Management data. Error rate = Number of incident reports/number of prescriptions filled

- **Measure 44017.01.01**

##### ***Compliance with laws and standards***

**Measure Type:** Outcome      **Measure Frequency:** Every Six Months

**Measure Baseline:** New measure; baseline data not available. Baseline to be established by December 2006

**Measure Target:** Each pharmacy is fully compliant with all applicable Board of Pharmacy regulations and has no repeat deficiencies by end of FY08.

**Measure Source and Calculation:**

Board of Pharmacy Inspection reports will be provided to VDH by the local health department pharmacist in charge, and will be used to calculate the percentage of compliant stand-alone pharmacies.

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#### **Objective 44017.01 Has the Following Strategies:**

- CHS will collaborate with the Central Pharmacy to institute a statewide and standardized incident reporting process for all service area customers who experience an "error" in pharmaceutical dispensing and develop a feedback mechanism to assure quality improvement.
- All dispensing will comply with VDH policies and procedures and Board of Pharmacy regulations.

#### **Objective 44017.02**

##### ***Reduce the cost of providing laboratory services in local health departments by reviewing current laboratory operations and implementing statewide standards for procedures and instrumentation***

Although each laboratory within the local health departments operates under CLIA regulations, operations can be enhanced by developing a statewide program to assure that all LHD laboratories employ common standards and share best practices. This will be accomplished by establishing and maintaining an inventory of laboratory procedures, instrumentation, personnel and expenditures offered by each local health department. Cost savings are expected to result from sharing expertise and resources among LHDs and considering ways to reduce costs of supplies and materials, training, and completion of laboratory submission forms.

#### **This Objective Supports the Following Agency Goals:**

- Promote systems, policies and practices that facilitate improved health for all Virginians.  
( This objective also aligns with the following Virginia long term objectives: To inspire and support Virginians toward healthy lives and strong, resilient families; and  
To be recognized as the best managed State in the Nation)

#### **This Objective Has The Following Measure(s):**

##### ● **Measure 44017.02.01**

###### ***Cost per laboratory test***

**Measure Type:** Outcome

**Measure Frequency:** Annually

**Measure Baseline:** New measure; baselined data not available. Baseline to be established by December 2006,

**Measure Target:** Ten percent (10%) reduction in costs, based on the four most frequently used tests across all health departments, by end of FY08.

###### **Measure Source and Calculation:**

Since this is a new measure and currently has no baseline data, the source of the information will come as a result of a statewide survey.

#### **Objective 44017.02 Has the Following Strategies:**

- The first step in implementing this measure is the design and administration of a statewide survey of local health department laboratory practices and expenditures. The survey results will serve as the baseline for subsequent comparisons. The survey will provide feedback to the local health districts comparing their practices to those in the rest of the state. Results of this survey will then be used to construct procedural and instrumentation standards across the state's health department laboratories, with particular attention paid to areas of standardization that will result in cost savings.
- The results will be reviewed and standards will be developed by a team of laboratory managers from the local health departments with CLIA moderate and high complexity labs, with technical input and expertise from DCLS.



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- Once standards are designed and implemented the local health departments will be surveyed on an annual basis to determine their compliance with the standards and savings realized.
- Technical assistance will be provided for those labs that have not met the standards and realized the cost savings.
- CLIA inspections will be reviewed to assure no repeat incidents or citations

#### **Objective 44017.03**

##### ***Laboratory services within local health departments will meet the quality standards established by CLIA with no repeat citations on audit or inspection***

Local health directors will assure that their respective laboratories maintain a CLIA Certificate of Compliance. Regular inspections will assure compliance with quality standards. A statewide inventory will be developed that compiles data on CLIA certification and citations for the laboratories within local health departments to share best practices.

##### **This Objective Supports the Following Agency Goals:**

- Promote systems, policies and practices that facilitate improved health for all Virginians.  
( This objective also aligns with Virginia's long term objective to inspire and support Virginians toward healthy lives and strong, resilient families.)

##### **This Objective Has The Following Measure(s):**

###### ● **Measure 44017.03.10**

###### ***Repeat CLIA Citations in VDH Laboratories***

**Measure Type:** Outcome      **Measure Frequency:** Annually

**Measure Baseline:** New measure; baseline data not available. Baseline to be established by December 2006.

**Measure Target:** Each laboratory fully compliant with applicable CLIA Regulations and will have no repeat CLIA citations by end of FY08.

###### **Measure Source and Calculation:**

Since this is a new measure and currently no baseline data, the source of the information will come as a result of a statewide survey of laboratory practices and expenditures. The survey results will serve as the baseline for subsequent comparisons.

##### **Objective 44017.03 Has the Following Strategies:**

- Survey Laboratories regarding their current CLIA certification (high, moderate or waived), including most recent inspection reports and citations. The survey will identify laboratories in need of technical assistance to meet certification requirements.
- VDH personnel in local health departments that have no repeat findings will provide technical assistance and consultation to those in need of compliance assistance.

#### **Objective 44017.04**

##### ***Reduce the administrative cost of providing pharmaceutical services in local health departments***

Pharmaceuticals for the management of chronic diseases, inborn errors of metabolism, biological terrorism, and other conditions may be provided through linkages with other VDH service areas, state, local, and federal agencies and pharmaceutical companies, private providers in the community through prescribed linkages, protocols, and referrals from and with other local health departments. An indicator

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of efficiency is how local health pharmacy costs compare to the private sector and this can be accomplished by identifying meaningful cost comparisons.

#### **This Objective Supports the Following Agency Goals:**

- Promote systems, policies and practices that facilitate improved health for all Virginians.  
( This objective is also aligned with Virginia's long term objective to be recognized as the best managed state in the nation.)

#### **This Objective Has The Following Measure(s):**

- **Measure 44017.04.00**

***Administrative cost per prescription***

**Measure Type:** Outcome      **Measure Frequency:** Annually

**Measure Baseline:** New measure, baseline to be determined by December 2006.

**Measure Target:** At least 10 percent below private sector administrative costs by end of FY08.

**Measure Source and Calculation:**

VDH Central Pharmacy and Budget Office to derive formula for determining administrative costs for filling a prescription through local health department pharmacy vs. private sector pharmacy

#### **Objective 44017.04 Has the Following Strategies:**

- Central Pharmacy and Budget Office will define cost to be included in the measure and apply this definition to determine a unit cost
- VDH Community Health Services (CHS) will use available data sources to obtain district and state average administrative costs per prescription
- Central Pharmacy and CHS will collaborate with private vendors to prepare comparative administrative cost analyses